Premarket (510k) Summary

K052392

Submitter Information:

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6581 City West Parkway
Eden Prairie, MN 55344
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MAY 04 2006

Contact: James D. Ecklein, Director RA/QA

Summary Date: January 13, 2006

Device Information:

Hot Dog Patient Warming System
DWJ 21 CFR Part 870.5900
Class II without exemption

Common Name: Patient Warming System

Predicate Devices:

Bair Hugger Model 750 – Arizant Medical, Inc. (K001149)
Chillbuster – Microtek Medical, Inc. (K022903)

Device Description:

The Hot Dog Patient Warming System is designed to compensate for body heat loss before, during and after surgery and in other situations in which a patient could become cold.

The device consists of four primary components, the outer Warming Blanket (disposable), the Warming Pad, Connecting, Cable and the Temperature Controller.

The outer Warming Blanket is placed atop the patient, and the Warming Pad is placed over the outer Warming Blanket.

The microprocessor based Temperature Controller uses 110-240 VAC line voltage and is connected to the Warming Pad via a cable. The Controller output to the Warming Pad is 48 VDC or less.

Intended Use:

The Hot Dog Patient Warming System is intended to prevent or treat hypothermia and to provide warmth to patients. The Hot Dog Patient Warming System should be used in circumstances in which patients could become cold.

The System is intended for use in hospitals and surgical centers including without limitation operating, recovery and emergency rooms, burn units and on medical/surgical floors.

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Functional and Safety Testing:

The System was evaluated in terms of achieved surface temperatures under normal operating conditions and in conditions of possible single fault failures to determine if an unacceptable risk of thermal injury existed.

Functional temperature testing shows that the warming system does not result in simulated skin temperatures that would cause thermal injury.

Safety system validation testing shows that all systems operate as intended. The primary and secondary over-temperature protection systems shut down power to the warming pad before pad surface temperatures reached unsafe temperatures.

Side-by-side testing of the electrically powered warming pads and the Bair Hugger™ Temperature management system showed similar performance for both devices. The average contact surface temperature for both devices falls into the 39 – 42 °C range in steady state testing.

Conclusion:

Based on the testing the "Hot Dog Patient Warm System™ is substantially equivalent to the Bair Hugger Model 750 Temperature Management System.

The Hot Dog Patient Warming System exhibits satisfactory temperature uniformity and responds satisfactorily in normal and single fault conditions

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2006

Augustine Biomedical & Design, LLC
c/o Mr. James Dr. Ecklein
Director of RA/QA
6581 City West Parkway
Eden Prairie, MN 55344

Re: K052392
Hot Dog Patient Warming System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II (Two)
Product Code: DWJ
Dated: February 27, 2006
Received: March 2, 2006

Dear Mr. Ecklein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Device Name: Hot Dog Patient Warming System

Indications for Use:

The Hot Dog Patient Warming System is intended to prevent or treat hypothermia and to provide warmth to patients. The Hot Dog Patient Warming System should be used in circumstances in which patients could become cold.

The system in intended primarily for use in hospitals and surgical centers including without limitation operating, recovery and emergency rooms, burn units and on medical/surgical floors.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052392